ABBOTT LABORATORIES

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Dockets Management Branch (HFA –305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20852

RE: *Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program [Docket 2004D-0352]*

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding the Global Harmonization Task Force (GHTF) document "Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program," GHTF/SG2(PD)/N38R14 published in the Federal Register on August 23, 2004 at 69 FR 51853.

Thank you for the opportunity to provide these comments. Our comments are presented by section of the guidance document.

Section 5.1 Associate Participants

Since the focus of the National Competent Authority Report (NCAR) Exchange Program is information regarding hazards associated with the use of medical devices, we recommend associate participants also undergo risk management training as a pre-requisite to participation. As described in the guidance document, associate participants are public, not-for-profit organizations that can make a significant contribution to the protection of public health. Given the influential role of such organizations, the focus of NCAR on hazards associated with medical devices, and the importance of fully understanding risk management principles, which as stated in the guidance document "consider more than hazard alone to determine whether remedial action is necessary," risk management training is appropriate.

Section 5.2 Full Participants

This section describes the prerequisites and commitments that apply to full participants in the National Competent Authority Report Exchange Program. Under this section, full participants must make a commitment to be a National Competent Authority. We recommend that this requirement be a prerequisite to participate, rather than a commitment. In accordance with this change, we also recommend updating the table in section 6.0.

2004D-0352

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Should you have any questions, please contact me at (847) 937-8197 or by facsimile at (847) 938-4422.

Sincerely,

April Veoukas

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